Licence Committee - minutes

Centre 0102 (Guy's Hospital)

Research Project R0133 - Renewal Inspection Report

Thursday, 13 July 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Lee Rayfield (Chair) Ruth Wilde Kate Brian Anita Bharucha	
Members of the Executive	Dee Knoyle Paula Robinson	Secretary Head of Planning & Governance
Legal Adviser	Philip Grey	Mills & Reeve LLP
Specialist Adviser		
Observers		

Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this item, however, they did want to declare the following:
- Lee Rayfield – HFEA Authority Member
- Kate Brian – HFEA Authority Member
- Ruth Wilde – HFEA Authority Member

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Executive summary
- Inspection report
- Application form
- Publications x 3
- Peer review
- Previous licensing minutes for last three years:
  - 26 February 2016 – interim inspection report
  - 26 June 2014 – update report
  - 13 March 2014 – renewal inspection report

1. Consideration of application

1.1. The committee noted that Guy's Hospital, centre 0102 is located in London. The centre currently holds a treatment and storage licence as well as research licences for two projects. Research project R0133, entitled 'Developing criteria for estimating quality of stem cells derived from human embryos', was first licensed in April 2002. The committee noted that the current licence is shortly due to expire on 31 July 2017. The committee noted that the Licence Holder for research project R0133 at centre 0102 is also a member of the Human Fertilisation and Embryology Authority.

1.2. The committee noted that the renewal inspection report and the executive summary were written appropriately for a lay person to understand the content.

1.3. The committee noted that the original application contained complex proposals which required high-level discussion within the HFEA. These proposals continue to be explored by the HFEA and will be formally considered by an appropriate committee in due course. As a result, the centre agreed to remove these proposals from the application for the current licence renewal.

1.4. The committee noted that when a renewal licence is granted, the Person Responsible (PR) has 28 days to consider the licence, however in this case, that period extends beyond the date of expiration of the current licence. Therefore, the Executive recommends that the Licence Committee issues Special Directions to enable the continuation of activity after the expiration of the current licence. The Special Directions should come into force from 1 August 2017 for a period of three months, or until the licence is accepted, whichever is sooner.

1.5. The committee noted that the application was made by the PR for the licence for the research project to be renewed for a period of three years.

1.6. The committee noted that the centre has applied for the following activities:

- creation of embryos in vitro
- keeping embryos
- use of embryos
- storage of embryos.

1.7. The committee noted that the proposed activities are to be licensed for the following purposes:

- Increasing knowledge about the causes of any other congenital disease or congenital medical condition
- Promoting advances in the treatment of infertility
- Increasing knowledge about the development of embryos

1.8. The committee noted that the treatment centres donating to this research project include:

- Guy's Hospital, centre 0102
- The Lister Fertility Clinic, centre 0006
- Sussex Downs Fertility Centre, centre 0015
- Herts and Essex Fertility Centre, centre 0030
- BMI Chelsfield Park ACU, centre 0086
- Nuffield Health Woking Hospital, centre 0144
- Chelsea and Westminster Hospital, centre 0158
- Salisbury Fertility Centre, centre 0197
- CARE Tunbridge Wells, centre 0208

1.9. The committee noted that this report covers the performance of the centre since the last inspection carried out on 10 December 2015. This report also covers findings from a robust desk-based evaluation of appropriate documentation, carried out on 13 April 2017 and communications received from the centre. The committee noted that at the time of the desk-based assessment no recommendations were made for improvement.

1.10. The committee noted that the research project has been approved by the St Thomas's Hospital Ethics Committee and evidence was provided by the PR that this approval remains active and covers the research activity described in the licence application.

1.11. The committee noted that the inspectorate recommends the renewal of the centre's licence for research project R0133 for a period of three years with no additional conditions.

1.12. The committee had regard to its decision tree.

1.13. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

1.14. The committee was satisfied that the activities to be licensed are necessary or desirable for the following purposes, specified in paragraphs 3A(1) and 3A(2) of Schedule 2 to the HFE Act 1990 (as amended):

- **Increasing knowledge about the causes of any other congenital disease or congenital medical condition**

  Work includes understanding more about serious genetic and mitochondrial diseases, and also understanding about the biopsy processes used in pre-implantation genetic diagnosis (PGD).

- **Promoting advances in the treatment of infertility**

  A subset of genetic diseases comprises those that cause infertility. Embryos with these genetic defects, identified by pre-implantation genetic diagnosis, are unsuitable for transfer. The justification for this is identical to that for genetic diseases in general.

- **Increasing knowledge about the development of embryos**

  Pre-implantation genetic diagnosis and pre-implantation genetic screening have traditionally sampled inner cell mass cells, but trophectoderm cells are now also sampled instead, based on the hypothesis that trophectoderm sampling improves embryo viability after testing. The research will compare the genomes of inner cell mass cells and trophectoderm cells: if they differ, this may invalidate trophectoderm-based testing; if they are identical, then this will be an important step in validating trophectoderm-based testing. In vitro twinned embryos will be used to help improve culture and stem cell derivation protocols.

1.15. The committee was satisfied that none of the proposed activities are prohibited by the HFE Act 1990 (as amended).

1.16. The committee was satisfied that the research licence renewal would not apply to more than one research project.

1.17. The committee noted that the use of human embryos is necessary for this research project for the following reason:

- Use of human embryos

  Research on the development of human embryos cannot be replaced by research on other animal embryos, as the detail of development varies substantially from species to species. Similarly, studying genetic diseases in non-human animal models while informative does not always properly identify a correct aetiology for human disease.

  Unused embryos will be obtained from IVF clinics with proper consent. Embryos will be created by artificial twinning in order to control for genetic difference when comparing the outcomes of different culture and derivation protocols. This idea is an important advance in the field and will improve the validity of studies to optimize culture and derivation.

  The derivation of human embryonic stem cell lines is for the purpose of differentiating them into tissue types relevant to the genetic defect which they carry. This is an established practice in the UK and elsewhere to study the aetiology of genetic diseases.

  The same aims/results could not be obtained if adult stem cell lines or induced pluripotent stem cells (iPSCs) were used. It is very possible to study genetic diseases using adult stem cells, but this approach does not reveal any changes that occur in embryogenesis or later development to adult that contribute to disease aetiology.

  It is very possible to study genetic diseases using induced pluripotent stem cells but this approach too does not reveal any changes that occur in embryogenesis or later development to adult that contribute to disease aetiology. Moreover the molecular detail of the process of the derivation of iPSCs is still uncertain, so human embryonic stem cells remain a gold standard in the field.

  The committee noted that no embryos have been used in the last year.

1.18. The committee was satisfied that the proposed research project does not involve the mixing of sperm with the egg of an animal.

1.19. The committee noted that the proposed research project does not involve the derivation of human embryonic stem cell lines for human application or the genetic modification of embryos.

1.20. The committee was satisfied that the PR possesses the required qualifications and experience and that the character of the PR is such as is required for supervision of the licensed activities. It was further satisfied that the PR will discharge their duties under section 17 of the HFE Act 1990 (as amended). The committee noted that the inspectorate was satisfied that the PR had satisfactorily completed the PR entry programme.

1.21. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

2. Decision

2.1. The committee agreed to renew the licence for research project R0133 at centre 0102, entitled 'Developing criteria for estimating quality of stem cells derived from human embryos', for a period of three years with no additional conditions with the following activities:

- creation of embryos in vitro
- keeping embryos
- use of embryos
- storage of embryos

for the following purposes:

- increasing knowledge about the causes of any other congenital disease or congenital medical condition
- promoting advances in the treatment of infertility
- increasing knowledge about the development of embryos.

2.2. The committee endorsed the Executive's recommendation to issue Special Directions to enable the continuation of activity after the expiration of the current licence, to allow the Person Responsible 28 days to consider the licence. The Special Directions will come into force from 1 August 2017 for a period of three months, or until the licence is accepted, whichever is sooner.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Bishop Lee Rayfield

Date

13 July 2017

Research Renewal Report: Desk based assessment

Purpose of this inspection report
The HFEA licenses and monitors establishments undertaking human embryo research. This is a report of an inspection, carried out to assess whether this centre complies with essential requirements when carrying out such research. Licences for individual research projects can be granted for up to three years and this report provides information on the centre's application for a renewal of its existing licence. The Authority's Licence Committee uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of assessment: 13 April 2017
Purpose of assessment: Renewal of a licence to carry out research
Assessment details:
The report covers the performance of the centre since the last inspection, findings from the desk based evaluation, and communications received from the centre. For this assessment, an inspector completed a robust desk-based evaluation of appropriate documentation. There was no site visit.
Inspector: Vicki Lamb
Date of Licence Committee: 13 July 2017
Centre Details:

Project title	Developing criteria for estimating quality of stem cells derived from human embryos
Centre name	Guy's Hospital
Centre number	0102
Research project number	R0133
Centre address	11th Floor, Tower Wing Assisted Conception Unit Guy's Hospital Great Maze Pond London SE1 9RT
Person Responsible (PR)	Dr Dusko Ilic
Licence Holder (LH)	Mr Yakoub Khalaf
Treatment centres donating to this research project	The Lister Fertility Clinic (0006) Sussex Downs Fertility Centre (0015) Herts and Essex Fertility Centre (0030) BMI Chelsfield Park ACU (0086) Guy's Hospital (0102) Nuffield Health Woking Hospital (0144) Chelsea and Westminster Hospital (0158) Salisbury Fertility Centre (0197) CARE Tunbridge Wells (0208)
Date licence issued	1 August 2014
Licence expiry date	31 July 2017
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

Centre 0102 is a treatment, storage and research centre. There are currently two research projects licensed at this centre. Research project R0133, entitled 'Developing criteria for estimating quality of stem cells derived from human embryos', was first licensed in April 2002.

The current licence is due to expire on 31 July 2017, having been renewed for three years by a Licence Committee on 13 March 2014. There are no additional conditions on the licence. The research project was last inspected on 10 December 2015.

Summary for licensing decision:

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

Administrative requirements:

- the centre has submitted an appropriately completed application form
- the centre has submitted the supporting information required by General Direction 0008, including evidence of ethics approval and patient information and consent forms have not changed since the last inspection.
- the application has designated an individual to act as the Person Responsible (PR)
- the proposed licence applies to one project of research
- the centre has submitted fees to the HFEA in accordance with requirements

Research activities applied for:

An application has been made for the following activities for the purpose of research:

- Creation of embryos in vitro
- Keeping embryos
- Using embryos
- Storage of embryos

The proposed research project does not involve the derivation of human embryonic stem cell lines for human application. Research licence conditions R41-89 are therefore not applicable to this research project.

Purposes for which research activities may be licensed:

The activities specified above are required by the PR for the following purposes, as defined in Schedule 2 3A (1) and (2) of the HF&E Act 1990 (as amended):

- Increasing knowledge about the causes of any other congenital disease or congenital medical condition
- Promoting advances in the treatment of infertility
- Increasing knowledge about the development of embryos

The PR and peer reviewer consider that the research project will meet the purposes defined in Schedule 2 3A (1) and (2) to the HF&E Act 1990 (as amended) as follows:

- Increasing knowledge about the causes of any other congenital disease or congenital medical condition

  The PR has stated:
  Work includes understanding more about serious genetic and mitochondrial diseases, and also understanding about the biopsy processes used in pre-implantation genetic diagnosis (PGD).

  The peer reviewer agrees and has stated:
  The applicants will continue to derive human embryonic stem cells containing genomes from patients with genetic (including mitochondrial) diseases at the request of third parties. The phenotype of these stem cells and their differentiated products may lead to a better understanding of the aetiology of these diseases.

- Promoting advances in the treatment of infertility

  The PR has stated:
  Some of the genetic diseases from which we will derive stem cells from PGD embryos unsuitable for transfer involve infertility as a result specifically of the genetic condition, eg. Robertsonian translocation in males, cystic fibrosis in males and fragile X syndrome in women.

  The peer reviewer agrees and has stated:
  A subset of genetic diseases comprises those that cause infertility. Embryos with these genetic defects, identified by pre-implantation genetic diagnosis, are unsuitable for transfer. The justification for this is identical to that for genetic diseases in general.

- Increasing knowledge about the development of embryos

  The PR has stated:
  By comparing the genetic constitution of inner cell masses isolated for stem cell research with trophectoderm from which it is separated, we can examine the consistency of findings between the two types of tissues, and thus establish the validity of genetic tests (PGD and PGS) made at the blastocyst stage.

  The peer reviewer agrees and has stated:
  Pre-implantation genetic diagnosis and pre-implantation genetic screening have traditionally sampled inner cell mass cells, but trophectoderm cells are now also sampled instead, based on the hypothesis that trophectoderm sampling improves embryo viability after testing. The research will compare the genomes of inner cell mass cells and trophectoderm cells: if they differ, this may invalidate trophectoderm-based testing; if they are identical, then this will be an important step in validating trophectoderm-based testing. In vitro twinned embryos will be used to help improve culture and stem cell derivation protocols.

Prohibited research activities:

The activities to be licensed are not prohibited by the HF&E Act 1990 (as amended) including those activities specifically prohibited by Sections 3, 3ZA, 4 or 4A, or by Schedule 2, paragraph 3 of the Act.

Use of embryos:

The use of human embryos is considered necessary. This is based on the application and comments by the peer reviewer:
Research on the development of human embryos cannot be replaced by research on other animal embryos, as the detail of development varies substantially from species to species. Similarly, studying genetic diseases in non-human animal models while informative does not always properly identify a correct aetiology for human disease.

The creation of embryos is justified according to the peer reviewer because:
Unused embryos will be obtained from IVF clinics with proper consent. Embryos will be created by artificial twinning in order to control for genetic difference when comparing the outcomes of different culture and derivation protocols. This idea is an important advance in the field and will improve the validity of studies to optimize culture and derivation.

The derivation of human embryonic stem cells is justified according to the peer reviewer because:
The derivation of human embryonic stem cell lines is for the purpose of differentiating them into tissue types relevant to the genetic defect which they carry. This is an established practice in the UK and elsewhere to study the aetiology of genetic diseases.

The same aims/results could not be obtained if adult stem cell lines or induced pluripotent stem cells (iPSCs) were used because:
It is very possible to study genetic diseases using adult stem cells, but this approach does not reveal any changes that occur in embryogenesis or later development to adult that contribute to disease aetiology.
It is very possible to study genetic diseases using induced pluripotent stem cells but this approach too does not reveal any changes that occur in embryogenesis or later development to adult that contribute to disease aetiology. Moreover the molecular detail of the process of the derivation of iPSCs is still uncertain, so human embryonic stem cells remain a gold standard in the field.

PR considerations:

The PR is suitable and has discharged their duty under Section 17 of the HF&E Act 1990 (as amended).

Premises:

The premises are suitable. This is based on information submitted with this application, and the previous inspection visit on 10 December 2015.

Recommendation

The Licence Committee is asked to note that at the time of the assessment there were no areas of practice that required improvement.

The inspector recommends the renewal of the centre's licence for a period of three years without additional conditions.

The inspection team recommends that the licence issued should include the following activities that the centre has applied for:

- Creation of embryos in vitro
- Keeping embryos
- Using embryos
- Storage of embryos

For the following purposes:

- Increasing knowledge about the causes of any other congenital disease or congenital medical condition
- Promoting advances in the treatment of infertility
- Increasing knowledge about the development of embryos

Section 2: Summary of the research project

This section summarises information submitted in the research licence application and from the Peer Reviewer.

Lay summary of the research project:

Stem cells are unique cell populations that are able to copy themselves exactly and also specialise into new cell types. The most powerful human stem cells can be isolated from the earliest stages of human development and they are termed human embryonic stem cells (hESC). These cells have great potential in regenerative medicine because they can be guided to form various more specialised cell types which then may be of use in treating serious debilitating diseases such as diabetes, or to repair organs following stroke or heart attacks. Another valuable use of these cells is in studying disease progression as well as in the search for new drugs for treatment of serious illnesses. Although there has been a lot of hype about stem cells, their potential is not yet fully realised. Firstly, methods to generate the cells in a reliable and safe way have to be established. Secondly, the characteristics of the cells have to be precisely defined, which has not yet been achieved - scientists have not been able to fully track and understand changes happening during manipulation of the cells. In this project, the researchers wish to define norms and standardise protocols that would assure quality and reliability of these cells. They plan to accurately analyse how the cells copy themselves and what factors make this process more successful, such as the position of each cell in a population or the addition of external supplements. This understanding will enable them to improve the methods they use to grow the cells. They will also look at the number and arrangement of the genetic material in the cells at the beginning of the culture and again several months later to see if any changes have occurred. Even minor alterations are cause for concern and may limit the use of these particular cells. Although hESC can become any other mature cell in an adult organism, they are usually inclined to go one way rather than another and it is not yet understood why. In this project the researchers will allow the cells to differentiate and study which cell types they prefer to become. Knowing the difference in preferences of hESC lines will be of great benefit to all researchers when selecting which cell line to use in experiments. The cells that already prefer to make muscle, for example, can be chosen for work on heart disease, whereas others that would rather make neural tissue can be used in treatment of spinal cord injuries. Lastly they will look for changes that are related uniquely to specific diseases and try to identify ways to prevent or reduce these changes. Detailed characteristics of any lines developed and studied will be logged with the cell line in the UK Stem Cell Bank for the benefit of all researchers and people that will use them in the future.

Objectives of the research:

1.To continue derivation of disease-specific hESC lines on demand.
2.To utilise hESC-derivation technology in the validation of blastocyst quality.

Summary of the research undertaken to date:

Since April 2013 the researchers have not derived any hESCs with clinically relevant genetic mutations. Derivation of hESC lines from normal embryos has been used as a quality control of manipulated embryos.

Donation and use of embryos:

In the period from 1 January 2016 to 31 December 2016, the centre did not use any embryos, and no embryos were created for use in the project. This was due to funding coming to an end. The project will continue, but at a reduced rate due to limited funding.

A total of 44 cell lines have been derived since the start of this research project.

Peer review comments:

The peer reviewer considers that it is appropriate to carry out the research.

Section 3: Details of the inspection findings

Principle:

3. Have respect for the special status of the embryo when conducting licensed activities.

What we inspected against:

Research Licence Conditions (RLC) R23, R24, R26, R27, R28, R29, CoP Guidance Note 22.

What the centre does well.

Observations during the last inspection in December 2015 provided assurance that the special status of the human embryo is respected:

- processes, documented in standard operating procedures (SOPs), are in place to ensure that no embryo obtained for the purposes of any research project is kept or used for any purpose other than the purposes of that research project (RLC R23). Staff training and their close supervision ensure procedures are adhered to, preventing the use of donated embryos in unlicensed activities.
- recruitment practices ensure that no money or other benefit is given to those donating embryos to research unless authorised by directions (RLC R24).
- each embryo used in the research project is uniquely labelled (RLC R26).
- documented procedures have been established, implemented and complied with to ensure that clinical and research roles are separated (RLC R27).
- procedures ensure that embryos do not develop after 14 days or the primitive streak has appeared (if earlier) (RLC R28). The culture and manipulation of each embryo is recorded in the laboratory records, which are regularly reviewed.
- when human embryonic stem cell lines are derived, a sample of all stem cell lines is deposited in the UK Stem Cell Bank (RLC R30).

What they could do better.

Nothing noted.

Principle:

5. Provide prospective and current patients and donors with sufficient, accessible and up-to-date information in order to allow them to make informed decisions.

6. Ensure that patients and donors have provided all relevant consents, before any licensed activity is undertaken.

What we inspected against:

Information, counselling and consent; CoP Guidance Note 22, RLC R18, R19, R20, R21, R22. Consent for storage; CoP Guidance Note 22, RLC R31, R32, R33, R34, R35, R36, R37, R38, R39.

What the centre does well.

Provision of information and counselling to those consenting to donate to research

Prior to giving consent, those donating to research should be provided with relevant information, and given a suitable opportunity to receive counselling about the implications of their donation. The PR has provided assurance that:

- prior to giving consent, those donating to research are given a suitable opportunity to receive proper counselling about the implications of their donation (RLC R18).
- necessary information is provided to patients prior to giving their consent (RLC R19 and R20).
- information is provided to patients by trained personnel in a manner and using terms that are easily understood (RLC R21). The competence of staff at the recruiting centres to provide information in this way, and to seek consent, has been assessed.
- a designated individual, who is not directly involved in the patient's treatment, is available to discuss with the patient the project of research and the possibility of donating material to the project (RLC R22). Contact details for this designated individual are provided in the patient information.

Consent for storage

Stored embryos are obtained only from centres to which a HFEA licence applies (RLC R33).

No embryos are kept in storage for longer than the statutory storage period (RLC R36, R38 and R39), or the period specified in a patients' consent if less than the statutory storage period.

What they could do better.

Nothing noted

Principle:

8. Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose.

What we inspected against:

Premises and facilities; RLC R10

What the centre does well.

Premises and facilities

The premises are suitable for carrying out the licensed activities (RLC R10). This conclusion is based on the centre's SAQ and the last research inspection visit in December 2015.

What they could do better.

Nothing noted

Principle:
10. Maintain proper and accurate records and information about all licensed activities

What we inspected against:
Information and record keeping; RLC R13, R14, R15, R16, R17, General Direction 0002.

What the centre does well.

The PR has provided all necessary information requested during this assessment within the required timescales.

Since the last inspection, the centre has submitted the annual research information and data sheet to the HFEA within the required timeframes (RLC R14 & General Direction 0002).

What they could do better.
Nothing noted

Principle:
11. Report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately

What we inspected against:
Incidents; RLC R40

What the centre does well.

Processes are in place to detect, report to the HFEA and investigate adverse incidents (RLC R40).

What they could do better.
Nothing noted

Principle:
12. Ensure that all licensed research by the centre meets ethical standards, and is done only where there is both a clear scientific justification and no viable alternative to the use of embryos.

What we inspected against:
HF&E Act 1990 (as amended), Schedule 2 (3(5) and 3A).

What the centre does well.
The research project has been approved by the St Thomas's Hospital Ethics Committee.

Evidence was provided by the PR that this approval remains active and covers the research activity described in the licence application.

The research project does not include any activities that have been prohibited by the HF&E Act 1990 (as amended).

A peer review was obtained for this renewal application and it is supportive of the licence renewal. Justifications that the activities to be licensed are necessary or desirable to meet the statutory purposes, have been provided by the PR and the peer reviewer, as discussed in detail in the 'Summary for Licensing Decision'. The PR and Peer Reviewer have also provided reasons why the use of human embryos is necessary and the proposed number of embryos to be used is justified.

What they could do better.
Nothing noted

Principle:
13. Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK, including:
- maintaining up-to-date awareness and understanding of legal obligations;
- responding promptly to requests for information and documents;
- co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare.

What we inspected against:
Licensing; RLC R1, R2, R3, R5, R6. The Person Responsible; HF&E Act 1990 (as amended) Section 16 & 17, RLC R8, R9.

What the centre does well.

Licensing
Information obtained at the last inspection, a review of the SAQ and discussions with the PR confirm that all licensed research activities will be performed only at the licensed premises under the supervision of the PR (RLC R1).

The Person Responsible
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary legal responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:
- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

The PR has suitable qualifications and experience for the activity authorised by the licence (HF&E Act 1990 (as amended), Section 16 (2)(ca)). The PR has successfully completed the HFEA PR Entry Programme (R1184/8). The inspector team considers that the PR has fulfilled his responsibilities under Section 17 of the HF&E Act 1990 (as amended).

What they could do better.
Nothing noted

Section 4: Monitoring of the centre's performance

Following an interim inspection in 2015, no recommendations for improvement were made.

Section 5: Areas of practice that require the attention of the Person Responsible

The section sets out matters which the inspection team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Act, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major areas of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" area of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates a departure from good practice.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
None			

Additional information from the Person Responsible
Thank you for sending us the draft inspection report. We are quite happy with it.